Remarks:

The above amendments and these remarks are responsive to the Office action dated September 20, 2005.

Prior to entry of this Amendment, claims 1-28 remained pending in the application. However, in the Office action, the Examiner considered only claims 1-10, claims 11-28 having been withdrawn pursuant to an earlier restriction/election requirement. Applicants hereby confirm the earlier provisional election of claims 1-10 (Invention I), and thus cancel claims 11-28 without prejudice.

Claims 1-3 and 6-8 stand rejected under 35 U.S.C. §102(b) based on Voss et al. (US 4,322,449). Claims 9 and 10 stand rejected under 35 U.S.C. §103(a) based on Voss et al. Claims 4-5 stand rejected under 35 U.S.C. §103(a) based on Voss et al. in view of Voges (US 6,894,841). Applicants respectfully traverse these rejections for the reasons set forth below.

Furthermore, applicants also have added new claims 29-34, which claims are properly considered with Invention I (as defined by the Examiner), and are fully supported by the specification as originally filed.

In view of the amendments above, and the remarks below, applicants respectfully request reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC § 102

As noted, claims 1-3 and 6-8 stand rejected under 35 U.S.C. §102(b) based on Voss et al. Voss et al. discloses a method for the preparation of pharmaceuticals using a piezoelectric dosing system to dot liquid, dissolved or suspended active substance onto a pharmaceutical carrier. Voss et al. does not disclose any selection

of position of dots, or any basis for making such a selection. In fact, Voss et al. does not even consider any relationship between dot placement and dissolution rate of the active substance (or between dot placement and surface-to-mass ratio of the resulting dots). Placement of the dots in Voss et al. thus is completely independent of any desired dissolution rate of the active substance (and of any surface-to-mass ratio of the resulting dots).

Claim 1 recites:

> 1. A method of controlling a dissolution rate of a bioactive agent, the method comprising:
> applying a first drop of solution carrying the bioactive agent at a first selected location on a delivery substrate; and
> positioning a second drop of solution carrying the bioactive agent at a second selected location on the delivery substrate, wherein the location of the first drop and the location of the second drop are selected based on a target dissolution rate.

Claim 1 thus expressly recites that "the location of the first drop and the location of the second drop are selected based on a target dissolution rate." As noted, Voss et al. does not even consider a target dissolution rate, much less select location for placement of drops based on target dissolution rate.

For at least the foregoing reasons, Voss et al. does not anticipate claim 1, and the rejection of claim 1 under 35 U.S.C. §102(b) based on Voss et al. should be withdrawn. Claims 2, 3 and 6-8 depend from claim 1, and are distinguishable for at least the same reasons as claim 1.

Additionally, as amended, claim 3 recites that "the first drop and the second drop are spaced sufficiently to avoid coalescing." Voss et al. does not disclose any desired spacing of droplets, and thus does not anticipate selecting spacing between the first and second drops "sufficiently to avoid

coalescing." Claim 3 thus is distinguished from Voss et al. for at least this additional reason.

Rejections under 35 USC § 103

Claims 9 and 10

Claims 9 and 10 stand rejected under 35 U.S.C. §103(a) based on Voss et al. As noted above, Voss et al. discloses a method for the preparation of pharmaceuticals using a piezoelectric dosing system to dot liquid, dissolved or suspended active substance onto a pharmaceutical carrier.

Voss et al., however, does not disclose or suggest placement of first and second drops at locations "selected based on a target dissolution rate," as recited in claim 1 (from which claims 9 and 10 depend). Claims 9 and 10 thus are distinguished from Voss et al. for at least the same reasons as claim 1. Accordingly, the rejection of claims 9 and 10 under 35 U.S.C. §103(a) based on Voss et al. must be withdrawn.

Furthermore, as noted by the Examiner, Voss et al. "fails to specifically teach the standard deviation regarding the spacing or overlapping of droplets." This is the subject matter of claims 9 and 10. Although the Examiner asserts that it would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot, the Examiner gives no indication of any such motivation for uniformity in dosing in the cited reference. Applicants respectfully request that the Examiner specify where such motivation is found. Absent such a showing, the rejection of claims 9 and 10 under 35 U.S.C. §103(a) based on Voss et al. must be withdrawn for at least this additional reason.

The Examiner also equates a desire for consistency of dosage with a standard deviation (either of the mean spacing between drops or of the mean overlap of drops) of less than 15% with "consistent spacing from dot to dot." The Examiner has, however, failed to provide any showing that equates consistent spacing with a corresponding spacing or overlap of "less than 15%." Applicants respectfully request that the Examiner demonstrate support for this proposition.

Claims 4 and 5

Claims 4-5 stand rejected under 35 U.S.C. §103(a) based on Voss et al. in view of Voges. As noted above, Voss et al. discloses a method for the preparation of pharmaceuticals using a piezoelectric dosing system to dot liquid, dissolved or suspended active substance onto a pharmaceutical carrier. Voges discloses an inhaler-type dispenser of a physiologically active substance using either a piezoelectric ejection device or a thermal "bubble jet" ejection device. As described, the Voges dispenser includes a mouthpiece for use in applying the physiologically active substance directly to the user.

Neither reference discloses or suggests placement of first and second drops at locations "selected based on a target dissolution rate," as recited in claim 1 (from which claims 4 and 5 depend). Claims 4 and 5 thus are distinguished from Voss et al. and Voges for at least the same reasons as claim 1. Accordingly, the rejection of claims 4 and 5 under 35 U.S.C. §103(a) based on Voss et al. in view of Voges must be withdrawn.

Furthermore, as noted, Voges et al. is specifically intended for use in dispensing a physiologically active substance into a user's mouth (without the use of a delivery substrate). Given such a delivery mechanism, there is no motivation or

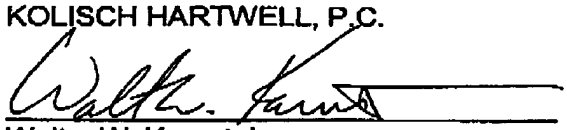
suggestion to use the teachings of Voges in effecting spacing of drops on a delivery substrate. In fact, the proposed delivery mechanism of Voges is antithetical to selecting and achieving a desired spacing of drops. The combination of Voss et al. and Voges thus is inappropriate, and the rejection of claims 4 and 5 under 35 U.S.C. §103(a) based on Voss et al. in view of Voges must be withdrawn.

Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

KOLISCH HARTWELL, P.C.



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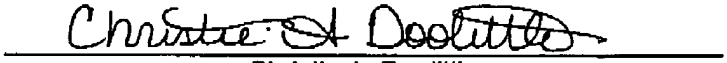
CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner J. Michener, Group Art Unit 1762, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on December 20, 2005.



Christie A. Doolittle